REMARKS

I. Introduction

Claims 11 to 25 are pending in the present application. In view of the foregoing amendments and the following remarks, it is respectfully submitted that all of the presently pending claims are allowable, and reconsideration is respectfully requested.

II. Rejection of Claims 11 to 13 and 20 to 22 Under 35 U.S.C. § 102(b)

Claims 11 to 13 and 20 to 22 were rejected under 35 U.S.C. 102(b) as anticipated by U.S. Patent No. 3,655,123 ("Judson et al."). Applicant respectfully submits that Judson et al. do not anticipate the present claims for the following reasons.

Claim 11 relates to a device for processing cell suspensions for autotransfusion. Claim 11 recites that the device includes at least one separation unit for separating cells by centrifugation. Claim 11 has been amended without prejudice herein to recite that the separation unit comprises a suspension inlet line and a concentrated cell outlet line having a pump under the control of a controller, and a waste line each located downstream of the suspension inlet line. Support for this amendment can be found, for instance, at page 7, lines 12 to 14 of the Specification which states "[c]ontrol unit 19 is also connected to ... concentrate pump 11 ... [such that] the delivery rates of pump[ ] 11 can be set by the control unit." Applicant maintains that this amendment does not raise new issues for consideration by the Examiner, because this limitation is already under consideration by the Examiner in connection with claims 15 and 23. Claim 11 also recites that the concentrated cell outlet line is connected to a diluting device. Claim 11 also recites that the dilution device is in fluid connection with the concentrated cell outlet line via a solution line for delivering physiologic solution. Claim 11 has been amended herein without prejudice to recite that cells contained in a suspension entering the separation unit through the inlet line under the control of the controller are concentrated in the separation unit, removed through the concentrated cell outlet line, and diluted via the diluting device with a physiologic solution. Support for this amendment can be found, for instance, at page 7, lines 10 to 14 of the Specification which states "an occluding delivery pump 17 connected to inlet line 16 is also

connected to a central control unit 19 by a control line 18 ... [such that] the delivery rates of pump[ ] 17 can be set by the control unit." Applicant maintains that this amendment does not raise new issues for consideration by the Examiner, because this limitation is already under consideration by the Examiner in connection with claims 14 and 23.

Judson et al. purport to disclose a continuous flow blood separator. The Final Office Action states that "Judson et al[.] teach a blood centrifugation device comprising a centrifuge (52) having a blood suspension inlet (90), a waste line and a concentrated cell outlet line with a concentrated cell pump (66) and a diluting device (76) in fluid connection with the concentrated cell outlet line via plasma outlet line from centrifuge (52) for delivering plasma e.g. physiologic solution via plasma pump (70) wherein plasma combines with the concentrated red blood cells to inherently dilute concentrated red blood cells because plasma is of lighter fluid than red blood cells (see figure 1; col. 7, line 29- col. 10, line 57)." Final Office Action at page 2.

It is respectfully submitted that Judson et al. do not anticipate claim 11 for at least the reason that Judson et al. do not disclose, or even suggest, all of the features recited in claim 11. For example, Judson et al. fail to disclose, or even suggest, a concentrated cell outlet line having a pump under the control of a controller, nor that cells contained in a suspension enter the separation unit through the inlet line under the control of the controller as recited in amended claim 11. Rather, Judson et al. do not describe any controller or control means that controls the red cell pump 66 of Judson et al. nor any controller or control means that controls the flow of solution through the line 90 from buffer bag 64. Thus, Judson et al. fail to disclose, or even suggest, either a concentrated cell outlet line having a pump under the control of a controller or that cells contained in a suspension enter the separation unit through the inlet line under the control of the controller, as recited in amended claim 11.

To anticipate a claim, each and every element as set forth in the claim must be found in a single prior art reference. Verdegaal Bros. v. Union Oil Co. of Calif., 814 F.2d 628, 631, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987). Furthermore, "[t]he identical invention must be shown in as complete detail as is contained in the . . . claim." Richardson v. Suzuki Motor Co., 868 F.2d 1226, 1236, 9 U.S.P.Q.2d 1913, 1920 (Fed. Cir. 1989). That is, the prior art must describe the elements

arranged as required by the claims. In re Bond, 910 F.2d 831, 15 U.S.P.Q.2d 1566 (Fed. Cir. 1990). As more fully set forth above, it is respectfully submitted that Judson et al. do not disclose, or even suggest, all of the features recited in amended claim 11.

Additionally, to reject a claim under 35 U.S.C. § 102, the Examiner must demonstrate that each and every claim limitation is contained in a single prior art reference. See, Scripps Clinic & Research Foundation v. Genentech, Inc., 18 U.S.P.Q.2d 1001, 1010 (Fed. Cir. 1991). Still further, not only must each of the claim limitations be identically disclosed, an anticipatory reference must also enable a person having ordinary skill in the art to practice the claimed invention, namely the inventions of the rejected claims, as discussed above. See, Akzo, N.V. v. U.S.I.T.C., 1 U.S.P.Q.2d 1241, 1245 (Fed. Cir. 1986). In particular, it is respectfully submitted that, at least for the reasons discussed above, the reference relied upon would not enable a person having ordinary skill in the art to practice the inventions of the rejected claims, as discussed above. Also, to the extent that the Examiner is relying on the doctrine of inherency, the Examiner must provide a "basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristics necessarily flows from the teachings of the applied art." See M.P.E.P. § 2112; emphasis in original; and see, Ex parte Levy, 17 U.S.P.Q.2d 1461, 1464 (Bd. Pat. App. & Inter. 1990). Thus, the M.P.E.P. and the case law make clear that simply because a certain result or characteristic may occur in the prior art does not establish the inherency of that result or characteristic. Accordingly, the anticipation rejection as to the rejected claims must necessarily fail for the foregoing reasons.

In summary, it is respectfully submitted that Judson et al. do not anticipate claim 11.

As for claims 12, 13 and 20 to 22, which ultimately depend from claim 11 and therefore include all of the limitations of claim 11, it is respectfully submitted that Judson et al. do not anticipate these dependent claims for at least the same reasons given above in support of the patentability of claim 11.

III. Rejection of Claims 11, 12 and 20 to 22 Under 35 U.S.C. § 102(b)

Claims 11, 12 and 20 to 22 were rejected under 35 U.S.C. 102(b) as anticipated by U.S. Patent No. 5,419,759 ("Naficy"). Applicant respectfully submits that Naficy does not anticipate the present claims for the following reasons.

Naficy purports to disclose an extracorporeal apparatus and methods for treatment of HIV (Human Immuno-deficiency Virus) infections and AIDS. According Naficy, infected blood is drawn from a patient and separated into infected components (comprising plasma, cell-free virus, and infected white cells containing replicating virus) and uninfected components (comprising red cells and platelets). Naficy states that the uninfected components are returned to the patient and the infected components are treated with organic agents and that the preferred organic agent is diethyl ether which is used in an amount and over a period of time sufficient to kill the infected cells and the cell-free virus. According to Naficy, the preferred apparatus functions at temperatures below 56.degree. C., and includes centrifugal separators for separating the infected components from healthy components; mixers and agitators inside an air-tight chamber void of oxygen where the infected components are mixed and treated with ether; centrifuges and distillators working under vacuum which remove the ether after the completion of treatment; a gas chromatograph with automatic sampling for determining the residues of ether and the safety of the treated components; and mechanisms for returning the treated and safe components, in conjunction with intravenous fluids, separately or together with the healthy components, to the patient.

The Final Office Action states that "Naficy teaches a blood centrifugation device comprising a centrifuge (14) having a blood suspension inlet, a waste line and a red concentrated cell outlet line and a diluting device i.e. intravenous fluid source in fluid connection with the red concentrated cell outlet line via a[n] intravenous fluid solution line (22) for delivering intravenous fluids combine[d] with the concentrated red blood cells to inherently dilute concentrated red blood cells because intravenous fluid is of a lighter fluid than red blood cells (see figure 1; col. 12, line 61 - col. 13, line 4)." Final Office Action at page 2.

It is respectfully submitted that Naficy does not anticipate claim 11 for at least the reason that Naficy does not disclose, or even suggest, all of the features recited in claim 11. For example, Naficy fails to disclose, or even suggest, a concentrated cell outlet line having a pump under the control of a controller, nor that cells contained in a suspension enter the separation unit through the inlet line under

the control of the controller as recited in amended claim 11. Rather, Naficy does not describe any controller or control means that controls the pump 24 of Naficy nor any controller or control means that controls the flow of intravenous fluids 22. Thus, Naficy fails to disclose, or even suggest, either a concentrated cell outlet line having a pump under the control of a controller or that cells contained in a suspension enter the separation unit through the inlet line under the control of the controller, as recited in amended claim 11.

Therefore, for at least the reasons stated above, it is respectfully submitted that Naficy does not anticipate claim 11.

As for claims 12 and 20 to 22, which ultimately depend from claim 11 and therefore include all of the limitations of claim 11, is respectfully submitted that Naficy does not anticipate these dependent claims for at least the same reasons given above in support of the patentability of claim 11.

IV. Rejection of Claim 19 Under 35 U.S.C. § 103(a)

Claim 19 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Judson et al. or Naficy. It is respectfully submitted that neither Judson et al. nor Naficy, either separately or in combination, render obvious the present claims as amended herein for the following reasons.

With respect to claim 19, the Final Office Action contends that"[c]laim 19 essentially differs from the apparatus of Judson et al. or Naficy in reciting that the separation unit has a shape selected from the group consisting of a ring or a spiral." Final Office Action at page 3. The Final Office Action concludes that "[i]t would have been an obvious matter of design choice to modify the separation unit in a shape of ring or spiral, since applicant has not disclosed that the separation unit in a shape of ring or spiral solves any stated problem or is for any particular purpose and it appears that the invention would perform equally well with any other shape such as square or diamond." Final Office Action at page 3.

It is respectfully submitted that neither Judson et al. nor Naficy disclose, or even suggest, all of the limitations recited in claim 19. For instance, claim 19 depends from claim 11 and therefore includes all of the limitations of claim 11. As stated above, neither Judson et al. nor Naficy disclose, or even suggest, either a concentrated cell outlet line having a pump under the control of a controller

or that cells contained in a suspension enter the separation unit through the inlet line under the control of the controller, as recited in amended claim 11.

In rejecting a claim under 35 U.S.C. § 103(a), the Examiner bears the initial burden of presenting a prima facie case of obviousness. In re Rijckaert, 9 F.3d 1531, 1532, 28 U.S.P.Q.2d 1955, 1956 (Fed. Cir. 1993). To establish prima facie obviousness, three criteria must be satisfied. First, there must be some suggestion or motivation to modify or combine reference teachings. In re Fine, 837 F.2d 1071, 5 U.S.P.Q.2d 1596 (Fed. Cir. 1988). This teaching or suggestion to make the claimed combination must be found in the prior art and not based on the application disclosure. In re Vaeck, 947 F.2d 488, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991). Second, there must be a reasonable expectation of success. In re Merck & Co., Inc., 800 F.2d 1091, 231 U.S.P.Q. 375 (Fed. Cir. 1986). Third, the prior art reference(s) must teach or suggest all of the claim limitations. In re Royka, 490 F.2d 981, 180 U.S.P.Q. 580 (C.C.P.A. 1974). As indicated above, neither Judson et al. nor Naficy disclose, or even suggest, all of the limitations recited in claim 19, because neither Judson et al. nor Naficy disclose, or even suggest, either a concentrated cell outlet line having a pump under the control of a controller or that cells contained in a suspension enter the separation unit through the inlet line under the control of the controller as recited in amended claim 11, from which claim 19 depends. It is therefore respectfully submitted that neither Judson et al. nor Naficy, either separately or in combination, render obvious claim 19.

Moreover, it is respectfully submitted that the cases of In re Fine, supra, and In re Jones, 21 U.S.P.Q.2d 1941 (Fed. Cir. 1992), make plain that the Final Office Action's generalized assertions that it would have been obvious to modify the reference do not properly support a § 103 rejection. It is respectfully submitted that those cases make plain that the Final Office Action reflects a subjective "obvious to try" standard, and therefore does not reflect the proper evidence to support an obviousness rejection based on the references relied upon. In particular, the Court in the case of In re Fine stated that:

> The PTO has the burden under section 103 to establish a *prima facie* case of obviousness. It can satisfy this burden only by showing some objective teaching in the prior art or that knowledge generally available to one of ordinary skill in the art would lead that individual to combine the relevant teachings of the references. This it has not done. . . .

> **Instead, the Examiner relies on hindsight in reaching his obviousness determination. . . . One cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention.**

In re Fine, 5 U.S.P.Q.2d at 1598 to 1600 (citations omitted; italics in original; emphasis added). Likewise, the Court in the case of In re Jones stated that:

> Before the PTO may combine the disclosures of two or more prior art references in order to establish *prima facie* obviousness, there must be some suggestion for doing so, found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. . . .
>
> **Conspicuously missing from this record is any evidence, other than the PTO's speculation (if it be called evidence) that one of ordinary skill . . . would have been motivated to make the modifications . . . necessary to arrive at the claimed [invention].**

In re Jones, 21 U.S.P.Q.2d at 1943, 1944 (citations omitted; italics in original).

That is exactly the case here since it is believed and respectfully submitted that the present Final Office Action offers no evidence whatsoever, but only conclusory hindsight, reconstruction and speculation, which these cases have indicated does not constitute evidence that will support a proper obviousness finding. Unsupported assertions are not evidence as to why a person having ordinary skill in the art would be motivated to combine or modify the references to provide the claimed subject matter of the claims to address the problems met thereby. Accordingly, the Office must provide proper evidence of a motivation for combining or modifying the references to provide the claimed subject matter.

More recently, the Federal Circuit in the case of In re Kotzab has made plain that even if a claim concerns a "technologically simple concept" -- which is not the case here -- there still must be some finding as to the "specific understanding or principle within the knowledge of a skilled artisan" that would motivate a person having no knowledge of the claimed subject matter to "make the combination in the manner claimed," stating that:

> In this case, the Examiner and the Board fell into the hindsight trap. The idea of a single sensor controlling multiple valves, as opposed to multiple sensors controlling multiple valves, is a technologically simple concept. With this simple concept in

> mind, the Patent and Trademark Office found prior art statements that in the abstract appeared to suggest the claimed limitation. But, there was no finding as to the specific understanding or principle within the knowledge of a skilled artisan that would have motivated one with no knowledge of Kotzab's invention to make the combination in the manner claimed. In light of our holding of the absence of a motivation to combine the teachings in Evans, we conclude that the Board did not make out a proper prima facie case of obviousness in rejecting [the] claims . . . under 35 U.S.C. Section 103(a) over Evans.

In re Kotzab, 55 U.S.P.Q.2d 1313, 1318 (Fed. Cir. 2000) (emphasis added). Again, it is believed that there have been no such findings.

Accordingly, there is no evidence that the references relied upon, whether taken alone or modified, would provide the features and benefits of claim 19. It is therefore respectfully submitted that claim 19 is allowable for these reasons.

V. Allowable Subject Matter

Applicants note with appreciation the indication that claims 23 to 25 are allowed. In addition, Applicants note with appreciation the indication of allowable subject matter contained in claims 14 to 18. Specifically, the Final Office Action states that "[c]laim 14 to 18 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claim." Final Office Action at page 4. Applicant has amended claim 14 so as to be rewritten in independent form including all of the limitations of its base claim, claim 11, and any intervening claims, e.g., claim 13. As such, claim 14 is in condition for immediate allowance. Furthermore, claims 15 to 18, which depend either directly or indirectly from claim 14, are also deemed to be in condition for immediate allowance by virtue of the amendments made herein to claim 14.

VI. Conclusion

It is therefore respectfully submitted that all of the presently pending claims are allowable. All issues raised by the Examiner having been addressed, an early and favorable action on the merits is earnestly solicited.

Respectfully submitted,

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